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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,229	04/11/2001	Avram Scheiner	279.337US1	2999

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/833,229	SCHEINER ET AL.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,56-65 and 73-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-19,56-65 and 73-77* is/are allowed.

6)☒ Claim(s) *20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (5,792,195) in view of Koestner et al. (5,300,093)

Regarding claim 20, Carlson et al. shows a first heart sound sensor, (34) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (26), an first interface circuit (42) and a first control circuit (32, 36, 38) that includes a bandpass filter (46), an ensemble averager (96, 98), a systole detector, where detection of systole triggers the ensemble averager (Fig. 2; Col. 6, lines 40 –55-Col. 7, line 13; Col. 7, lines 23-58) and an external system (40) with a second interface circuit.

Although Carlson et al. fails to show an output device configured to simultaneously output multiple signals; and a second control circuit coupled to the second interface circuit and the output device configured to receive the first, second, and third data and generate control signals causing the output device to simultaneously output at least the first, second and third sensed signals, attention is directed to Koestner et al. which shows an external monitor and display that is coupled telemetrically to an implantable medical device which is configured to receive the first, second, and third data, process the first data, and generate control signals causing the output device to simultaneously output at least the first, second and third sensed

signals and visual indicia (event annotations or markers) (Col. 27, line 9-Col. 32, line 52). Koestner et al. teaches that the simultaneous transmission and display of electrical signals and physiological signals allows the interrelationships between mechanical and electrical cardiac signals to be set forth quickly and easily and greatly enhances the diagnostic information available to the physician (Col. 32, lines 44-52). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the external system of Carlson et al. with the external system of Koestner et al. in order to quickly and easily set forth the interrelationships between mechanical and electrical cardiac signals and greatly enhance the diagnostic information available to the physician.

Regarding claim 21, Carlson et al. further shows the heart sound sensor is an accelerometer (34) located internal to the implantable housing (10)

With respect to claim 22, Carlson et al. shows the second sensor (24) includes an atrial sensing electrode (20, 22), and the third sensor (26) includes a ventricular sense electrode (16,18) wherein the second sensor is disposed in the right side of the heart.

Response to Arguments

3. Applicant's arguments with respect to claims 20-22 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

4. Claims 1-19, 59-65, 73-77 allowed.

Regarding clams 1-8, and 73-75, the prior art of record fails to teach or suggest an implantable device with a plurality of implantable heart sound sensors and a control circuit with a first and second processing paths, where the first processing path includes a first band pass

filter, a rectifier, a low pass filter and a first ensemble averager and a the second processing path includes a second band pass filter and a second ensemble averager.

With respect to claims 9-19, the prior art of record fails to teach or suggest a system including an implantable device including a first sensor, a second sensor, a first interface circuit and a first control circuit that includes a bandpass filter and an ensemble averager, coupled to the sensors and the interface circuit, configured to receive the first and second sensed signals, to generate first data representative of heart sounds from the first sensed sirgnals by filtering and averaging the signals, to generate second data representative of cardiac electrical signals from the second sensed signals, and to transmit the first data and the second data via the first interface; and an external device communicatively coupled to the implantable device, the external device including a second interface circuit; an output device including a display configured to simultaneously display multiple signals and a second control circuit, coupled to the second interface circuit and the output device, configured to receive the first data and the second data via the interface circuit, detect predetermined type heart sounds from the first data and predetermined type electrical cardiac events from the second data calculate at least one timing difference between an electrical cardiac event of the predetermined type electrical cardiac events and a heart sound of the predetermined type heart sounds and generate control signals causing the output device to simultaneously output at least the first sensed signals and the second sensed signals and the at least one timing difference.

Regarding claims 56-58, the prior art of record fails to teach or suggest a method comprising detecting heart sounds using a plurality of implanted sensors, generating first data representative of the heart sounds using band pass filtering and ensemble averaging; transmitting

the first data to an external system; and generating second data representative of the heart sounds using band pass filtering, rectification, low pass filtering, and ensemble averaging

With respect to claims 59-65, and 76-77, the prior art of record fails to teach or suggest a method including generating first data representative of heart sounds *in the implanted system*, receiving the data *from the implanted system*, generating control signals using the first data in combination with generating timing comparison control signals and applying the control signals and the timing comparison control signals to an output device to generate representations of heart sounds and timing information.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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kdm

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